

Application Number 10/723,316
Amendment dated January 8, 2007
Response to Office Action mailed August 7, 2006

RECEIVED
CENTRAL FAX CENTER
JAN 08 2007

REMARKS

This Amendment is responsive to the Final Office Action dated August 7, 2006, and is submitted with a Request for Continued Examination. Applicant has amended claims 1, 3-5, 7, 11, 14, 20-24, 28 and 30, cancelled claims 2, 6, 12, 13, 15-19, 31 and 32, and added claims 33-39. Claims 1, 3-5, 7-11, 14, 20-30 and 33-39 are pending.

Rejection for Obviousness-type Double Patenting:

The Office Action provisionally rejected, under the judicially created doctrine of obviousness-type double patenting: claims 1-27 and 30-32 as being unpatentable over claims 1-27 and 36-37 of copending Application No. 10/236,578; claims 7-8 as being unpatentable over claims 1, 7, 32 and 38 of copending Application No. 10/723,903; claims 7-8 as being unpatentable over claims 1, 7, 32 and 38 of copending Application No. 10/745,757; claim 27 as being unpatentable over claim 1 of copending Application No. 10/836,355; claim 27 as being unpatentable over claim 1 of copending Application No. 10/836,840; claims 7-8 as being unpatentable over claims 1 and 7 of copending Application No. 10/836,924; claims 7-8 as being unpatentable over claims 1 and 7 of copending Application No. 10/836,927; claim 27 as being unpatentable over claim 1 of copending Application No. 10/836,970; claim 27 as being unpatentable over claim 1 copending Application No. 10/837,181.

Applicant notes the provisional status of this rejection. Accordingly, Applicant will address this issue if and when the rejection is formally applied.

Interpretation of "Adjacent" is unreasonable

A number of the rejections of Applicant's claims are based on an unreasonable interpretation of the term "adjacent." The applied references fail to disclose delivery of stimulation via leads implanted adjacent to the specific locations recited in Applicant's claims. The applied references instead disclose different targets for stimulation.

Nonetheless, the Office Action rejected Applicant's claims based on these references. As one example, the Office Action stated that implantation of a medical lead adjacent to the sacral, pelvic splanchnic nerves and/or the pudendal nerves necessarily results in a lead implanted "adjacent" to the other, different locations recited in Applicant's independent claims. In other

Application Number 10/723,316
Amendment dated January 8, 2007
Response to Office Action mailed August 7, 2006

words, the Office Action interpreted the term "adjacent" so broadly such that the disclosure of a lead implanted anywhere within the pelvis would anticipate any specific target pelvic location recited by a claim.

This interpretation is unreasonable. One of ordinary skill would understand the term adjacent to require the absence of anything of the same kind in between, i.e., that the lead is more proximate to the recited target location than to the other nerve locations recited in the applied references.¹ The applied references do not suggest, much less provide an enabling disclosure of delivering stimulation to treat the specific disorders from leads implanted at the specific locations recited in Applicant's claims.

Claim Rejections Under 35 U.S.C. § 102

US 6,941,171 to Mann et al. (Mann)

The Final Office Action rejected claims 1-3, 6-9 and 11-32 under 35 U.S.C. § 102(e) as being anticipated by Mann. Applicant respectfully traverses this rejection to the extent the rejection is considered applicable to the claims as amended. Mann fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Mann fails to disclose or suggest a method comprising implanting a first medical electrical lead in tissue of a patient adjacent, around or in at least one of the bladder or portions thereof, the vagina or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacro-tuberous ligament or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, as required by independent claim 1, as amended.

Instead, as recognized in the Office Action, Mann merely describes stimulating a pudendal nerve and its branches, such as a portion at the pudendal canal, the dorsal nerve of the penis or clitoris, the urethral branch, or the inferior rectal branch. The general disclosure of pudendal nerve stimulation in Mann would not have suggested implantation of a lead in any of the specific locations recited by amended independent claim 1 to one of ordinary skill in the art.

¹ E.g., Merriam-Webster Online Dictionary, www.m-w.com.

Application Number 10/723,316
Amendment dated January 8, 2007
Response to Office Action mailed August 7, 2006

With respect to amended independent claim 28, Mann also fails to disclose or suggest a method for treating urinary retention disorder in a patient comprising implanting a first implantable medical electrical lead adjacent, around or in at least one of a pudendal nerve or branches or portions thereof, a hypogastric nerve or branches or portions thereof, a prostatic plexus nerve or branches or portions thereof, a sacral splanchnic nerve or branches or portions thereof, a pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof.

Mann does not teach or suggest treating urinary retention disorder, and, instead, describes treating incontinence, urgency, frequency, pelvic pain, and sexual dysfunction. Mann lacks any disclosure that suggests treating urinary retention disorder through implantation of a lead at any of the locations recited by amended claim 28. For at least these reasons, Mann fails to disclose or suggest the requirements of Applicant's amended independent claim 28.

Furthermore, with respect to amended independent claim 30, Mann fails to disclose or suggest a method for treating at least one of prostatitis, prostatalgia or prostatodynia in a patient, comprising implanting a first implantable medical electrical lead configured for implantation adjacent, around or in at least one of the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof.

Application Number 10/723,316
Amendment dated January 8, 2007
Response to Office Action mailed August 7, 2006

Instead, as recognized in the Office Action, Mann describes treating pelvic pain by stimulating a pudendal nerve or its branches. The general disclosure in Mann of using stimulation to treat pelvic pain would not have suggested treating prostatitis, prostalgia or prostatodynia through implantation of a lead at any of the locations recited by amended claim 30.

Applicant has cancelled independent claim 32 without prejudice.

Mann fails to disclose each and every limitation set forth in claims 1-3, 6-9 and 11-30. For at least this reason, the Office Action has failed to establish a *prima facie* case for anticipation of Applicant's claims 1-3, 6-9, 11-30 by Mann under 35 U.S.C. § 102(e). Withdrawal of this rejection is respectfully requested.

US 2005/0209652 to Whitehurst et al. (Whitehurst)

The Final Office Action also rejected claims 1-9, 11-20, 23, 25-27 and 32 under 35 U.S.C. § 102(e) as being anticipated by Whitehurst. Applicant respectfully traverses this rejection to the extent the rejection is considered applicable to the claims as amended. Whitehurst fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

Whitehurst, like Mann, fails to disclose or suggest a method comprising implanting a first medical electrical lead in tissue of a patient adjacent, around or in at least one of the bladder or portions thereof, the vagina or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacro-tuberous ligament or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, as required by independent claim 1, as amended.

Instead, as recognized in the Office Action, Whitehurst describes stimulating the penis, prostatic plexus, urethra, or pelvic splanchnic nerves. Whitehurst's disclosure would not have suggested implantation of a lead in any of the locations recited by amended independent claim 1 to one of ordinary skill in the art.

Whitehurst fails to disclose each and every limitation set forth in claims 1-9, 11-20, 23 and 25-27. For at least this reason, the Office Action has failed to establish a *prima facie* case for

Application Number 10/723,316
Amendment dated January 8, 2007
Response to Office Action mailed August 7, 2006

anticipation of Applicant's claims 1-9, 11-20, 23 and 25-27 by Whitehurst under 35 U.S.C. § 102(e). Withdrawal of this rejection is respectfully requested.

US 5,454,840 to Krakovsky et al. (Krakovsky)

The Final Office Action also rejected claims 1, 2, 7-8, 14-29 and 32 under 35 U.S.C. § 102(b) as being anticipated by Krakovsky. Applicant respectfully traverses this rejection to the extent the rejection is considered applicable to the claims as amended. Krakovsky fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Krakovsky fails to disclose or suggest a method comprising implanting a first medical electrical lead in tissue of a patient adjacent, around or in at least one of the bladder or portions thereof, the vagina or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacro-tuberous ligament or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof, as required by independent claim 1, as amended.

Instead, as recognized in the Office Action, Krakovsky describes stimulation of the pelvic splanchnic nerve or pudendal nerve for treatment of sexual dysfunction and stimulation of the urethra to correct female urinary incontinence during sexual intercourse. The disclosure of pelvic splanchnic nerve, pudendal nerve, and urethra stimulation in Krakovsky would not have suggested implantation of a lead in any of the locations recited by amended independent claim 1 to one of ordinary skill in the art.

In support of the rejection of Applicant's independent claim 1, the Office Action stated that implantation of a medical lead adjacent to the pelvic splanchnic nerves and/or the pudendal nerves necessarily results in a lead implanted adjacent to other nerves, because adjacent can be interpreted to mean close but not necessarily touching. As discussed above, Applicant respectfully suggests that this interpretation of the term "adjacent" is unreasonable. A lead implanted proximate to the pelvic splanchnic nerves and/or the pudendal nerves is not necessarily more proximate the specific targets recited in claim 1 than pelvic splanchnic nerves and/or the pudendal nerves themselves, or a host of other possible locations.

Application Number 10/723,316
Amendment dated January 8, 2007
Response to Office Action mailed August 7, 2006

With respect to amended independent claim 28, Krakovsky fails to disclose or suggest a method for treating urinary retention disorder in a patient comprising implanting a first implantable medical electrical lead configured for implantation adjacent, around or in at least one of a pudendal nerve or branches or portions thereof, a hypogastric nerve or branches or portions thereof, a prostatic plexus nerve or branches or portions thereof, a sacral splanchnic nerve or branches or portions thereof, a pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the penile dorsal nerve or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, Alcock's Canal or branches or portions thereof, sacro-tuberous ligament or branches or portions thereof, ischial tuberosity or branches or portions thereof, greater sciatic foramen or branches or portions thereof, or lesser sciatic foramen or branches or portions thereof.

Krakovsky does not teach or suggest treating urinary retention disorder, and, instead, describes treating sexual dysfunction and female urinary incontinence during sexual intercourse. Krakovsky lacks any disclosure that suggests treating urinary retention disorder through implantation of a lead at any of the locations recited by amended claim 28. For at least these reasons, Krakovsky fails to disclose or suggest the requirements of Applicant's amended independent claim 28.

Krakovsky fails to disclose each and every limitation set forth in claims 1, 2, 7-8 and 14-29. For at least this reason, the Office Action has failed to establish a *prima facie* case for anticipation of Applicant's claims 1, 2, 7-8, 14-29, and 32 by Krakovsky under 35 U.S.C. § 102(b). Withdrawal of this rejection is respectfully requested.

Application Number 10/723,316
Amendment dated January 8, 2007
Response to Office Action mailed August 7, 2006

Claim Rejection Under 35 U.S.C. § 102/103

In the Final Office Action, the Examiner rejected claims 1-2, 9, 14-19, 24 and 30-32 under 35 U.S.C. § 102(b), or in the alternative under 35 U.S.C. § 103(a), as being unpatentable over, "Neural Stimulation as a method of controlling prostatitis systems" (Chalfin), disclosed in 1999 Selected Abstracts from the American Urological Association annual meeting. Applicant respectfully traverses the rejection to the extent such rejections may be considered applicable to the claims as amended. Chalfin fails to disclose or suggest the inventions defined by Applicant's claims, and provides no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

In support of the rejection of Applicant's independent claims 1 and 30, the Office Action stated that implantation of a medical lead adjacent to the sacral nerve necessarily results in the lead being implanted adjacent to other nerves, because nerve structures are close together but not necessarily touching. As discussed above, Applicant respectfully suggests that this interpretation of the term "adjacent" is unreasonable. A lead implanted proximate to sacral nerve is not necessarily more proximate the specific targets recited in Applicant's independent claims than sacral nerve itself or a host of other possible locations.

In an alternative rejection, the Office Action stated that the passage of Chaflin which states "the therapy works by applying chronic electrical stimulation to sensory nerves that supply the bladder, rectum and pelvic floor," teaches that Chaflin contemplates stimulation of nerves other than the sacral nerves. In the first paragraph of Chaflin's article, Chaflin describes "unilateral sacral nerve stimulation" therapy and continues to describe the therapy in the second paragraph by stating that "the therapy works by applying chronic electrical stimulation to sensory nerves that supply the bladder, rectum and pelvic floor." In the second paragraph, Chaflin describes unilateral sacral nerve stimulation therapy in further detail and describes the sacral nerves as sensory nerves that supply the bladder, rectum and pelvic floor. Chaflin does not disclose or suggest stimulating any nerves other than sacral nerves, which supply the bladder, rectum and pelvic floor.

For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicant's claims 1-2, 9, 14-19, 24 and 30 under 35 U.S.C. §§ 102(b) and 103(a). Withdrawal of this rejection is requested

Application Number 10/723,316
Amendment dated January 8, 2007
Response to Office Action mailed August 7, 2006

Claim Rejections Under 35 U.S.C. § 103

In the Final Office Action, the Examiner rejected claims 4, 5 and 10 under 35 U.S.C. § 103(a) as being unpatentable over Mann; rejected claims 10, 21, 22 and 24 under 35 U.S.C. § 103(a) as being unpatentable over Whitehurst; and rejected claims 4-8 and 10-13 under 35 U.S.C. § 103(a) as being unpatentable over in view of US 6,055,456 to Gerber (Gerber). Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

As discussed above, Mann, Whitehurst, Krakovsky, and Chafin fail to disclose or suggest each of every feature of Applicant's independent claims 1, 28 and 30, as amended. Gerber does not provide any teaching that would have overcome the basic deficiencies of Mann, Whitehurst, Krakovsky, and Chafin with respect to the requirements of the independent claims. For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicant's claims 4, 5, 10, 21, 22 and 24 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

New Claims:

Applicant has added claims 33-39 to the pending application. No new matter has been added by the new claims. The applied references fail to disclose or suggest the inventions defined by Applicant's new claim, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

For example, the applied references fail to disclose or suggest delivering stimulation to a plurality of locations via a St. Mark's electrode, sensing an evoked response for each of the locations, selecting one of the locations based on the evoked responses, and implanting electrodes of the first lead adjacent, around, or in tissue at the selected location, as recited by claim 33 and new independent claims 36.

Further, the applied references fail to disclose or suggest a method for treating pelvic pain comprising providing an hermetically sealed implantable electrical pulse generator configured to

Application Number 10/723,316
Amendment dated January 8, 2007
Response to Office Action mailed August 7, 2006

provide at least one electrical stimulation pulse regime effective to at least partially treat pelvic pain in the patient, providing at least a first implantable medical electrical lead configured for implantation adjacent, around or in at least one of a hypogastric nerve or branches or portions thereof, a prostatic plexus nerve or branches or portions thereof, a sacral splanchnic nerve or branches or portions thereof, a pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacro-tuberous ligament or branches or portions thereof, the first lead comprising proximal and distal ends and at least one electrode, implanting the first lead in tissue of the patient adjacent, around or in at least one of a hypogastric nerve or branches or portions thereof, a prostatic plexus nerve or branches or portions thereof, a sacral splanchnic nerve or branches or portions thereof, a pelvic splanchnic nerve or branches or portions thereof, the prostate or branches or portions thereof, the pelvic floor, the colon or branches or portions thereof, the bladder or portions thereof, the vagina or portions thereof, the anus or portions thereof, the external anal sphincter or portions thereof, the urethra or portions thereof, inferior rectal nerves or branches or portions thereof, perineal nerves or branches or portions thereof, scrotal nerves or branches or portions thereof, the scrotum or portions thereof, sacro-tuberous ligament or branches or portions thereof, operably connecting the proximal end of the at least first lead to the implantable pulse generator, implanting the implantable pulse generator within the patient, and delivering electrical stimulation pulses from the implantable pulse generator to at least a portion of the tissue of the patient through the at least first lead and electrode, the pulses being provided in accordance with the electrical stimulation pulse regime and providing to the patient at least partial relief from pelvic pain, wherein the electrical stimulation pulses that are delivered to the desired nerve target sites or portions cause paresthesia, or the masking or blocking pain signals originating in or carried by a desired or target nerve or nerve portion located in the vicinity of the at least one electrode, as required by Applicant's claim 39.

Application Number 10/723,316
Amendment dated January 8, 2007
Response to Office Action mailed August 7, 2006

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

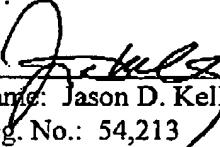
Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

1/8/07

SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

By:


Name: Jason D. Kelly
Reg. No.: 54,213